IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

DEFENDANTS' PRE-TRIAL BRIEF

Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, "Pfizer") respectfully submit this Pre-Trial Brief for the Court's consideration and in support of their proposed jury instructions.[1]

ARGUMENT

I. Plaintiff Will Be Unable To Satisfy Her Burden Of Proof Regarding Failure To Warn

A. Plaintiff's Remaining Claims Are Subsumed By Her Failure To Warn Claims

On May 26, 2009, the MDL Court dismissed "all fraud claims alleging affirmative misrepresentations or a suppression of information as a part of a national marketing campaign" and allowed only claims of misrepresentation by concealment of material information about the side effects of Neurontin. *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 618 F. Supp. 2d 96, 112-14 (D. Mass. 2009) [MDL Docket No. 1790]. On August 14, 2009, the MDL Court granted Pfizer's motion for summary judgment with respect to Plaintiff's express

[1] To the extent that this Court or the MDL Court have ruled on issues of law stated herein, they are included in order to preserve them for reconsideration by the Court prior to entry of judgment or for appeal.

warranty and Tennessee Consumer Protection Act claims. *See In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, MDL No. 1629, Memorandum & Order at 2-3 (D. Mass. Aug. 14, 2009) [MDL Docket No. 2060]. As a result, the only claims remaining are Plaintiffs' claims for negligence, product liability, breach of the implied warranty of fitness for a particular purpose and fraudulent concealment.

For each of her remaining claims, Plaintiff must establish, as a threshold matter, that the requirements of the Tennessee Products Liability Act of 1978, Tenn. Code Ann. §§ 29-28-101 to 29-28-108 (West 2002) ("TPLA"), have been satisfied. As the Sixth Circuit has explained:

> At the outset we note that . . . a "product liability" claim . . . is subject to the limits of the Tennessee Product Liability Act. Under the Act,
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> > "Product liability action" for purposes of this chapter includes all actions brought for or on account of . . . death . . . caused by or resulting from the . . . warning . . . of any product. "Product liability action" includes, but is not limited to, all actions based upon the following theories: strict liability in tort; negligence . . . .
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> *See* Tenn. Code Ann. § 29-28-102(6). For such claims, the Act's language is exclusive and preemptive: "A manufacturer or seller of a product *shall not be liable for any injury* to a person or property caused by the product *unless* . . . ." *Id.* § 29-28-105 (emphases added).

Privette v. CSX Transp., Inc., 79 Fed. Appx. 879, 890 (6th Cir. 2003) (third through sixth ellipses in original). Because all of Plaintiff's claim are based upon Defendants' alleged failure to provide adequate warnings with Neurontin, they are all subject to the TPLA and "must meet the requirements of the Act that are a prerequisite to any finding of liability." *Irion v. Sun Lighting, Inc.*, No. M2002-00766-COA-R3-CV, 2004 WL 746823, at *3 (Tenn. Ct. App. Apr. 7, 2004); *see also Shoemake v. Omniquip Int'l, Inc.*, 152 S.W.3d 567, 572-73 (Tenn. Ct. App. 2003).

Each of Plaintiff's claims is inextricably tied to her failure-to-warn claim, because they all require a duty to disclose and the only duty identified is the duty of a manufacturer to disclose known and foreseeable risks of a product. For example, it is well settled that an omission cannot be actionably misleading absent a duty to disclose. *See, e.g.*, *City of Monroe Employees Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 668 (6th Cir. 2005). In its summary judgment ruling on

Plaintiff's fraudulent omission claim, this Court referred to the duty of a manufacturer to disclose the risks associated with its product. (Feb. 19, 2010 Mem. [63] at 28-30.)[2]

As observed by the MDL Court, Plaintiff's claim for fraudulent omission differs from her failure to warn claim in that it has the ***additional*** element of scienter. In other words, Plaintiff would have to prove everything that she must to establish her failure to warn claim: (1) that Neurontin can cause suicide; (2) that Pfizer knew or should have known of the risk of suicide prior to 2004; and (3) that Neurontin caused Richard Smith's suicide; but she would have to establish the additional element that Pfizer acted not only negligently, but with intent. *See In re Neurontin*, 618 F. Supp. 2d at 113. In short, there is no circumstance under which a jury could properly find Defendants not liable for failure to warn but liable for fraudulent concealment. The additional element of scienter would not make Pfizer *more* liable for compensatory damages. Instead, it would be relevant, if at all, only on the issue of punitive damages.[3]

Likewise, this Court's analysis of Plaintiff's implied warranty claim rested upon the same factual predicate as her failure-to-warn claim. (Feb. 19, 2010 Mem. [MDLTenn. 63] at 26-27.) The jury instructions and verdict, therefore, should be drafted to avoid requiring the jury to decide the same failure-to-warn claim under different doctrinal labels. *See* Restatement (Third) of Torts: Products Liability § 2 cmt. n (1998) ("[T]wo or more factually identical failure-to-warn claims should not be submitted to the trier of fact in the same case under different doctrinal labels."). To do so would only confuse the jury, and invite inconsistent verdicts. *See, e.g.*,

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[2] For the reasons set forth in its prior Memorandum in Support of Motion for Summary Judgment [MDTenn 18 at 20], Defendants respectfully suggest that a manufacturer's duty to warn is not one of the duties that Tennessee courts have held can give rise to a fraudulent concealment claim. Instead, the "duty to disclose arises in three distinct circumstances: (1) '[w]here there is a previous definite fiduciary relation between the parties,' (2) '[w]here it appears one or each of the parties to the contract expressly reposes a trust and confidence in the other,' and (3) '[w]here the contract or transaction is intrinsically fiduciary and calls for perfect good faith." *Shah v. Racetrac Petroleum Co.*, 338 F.3d 557, 571 (6th Cir. 2003) (alterations in original) (quoting *Domestic Sewing Mach. Co. v. Jackson*, 83 Tenn. 418, 425 (1885)); *accord Morgan v. Brush Wellman, Inc.*, 165 F. Supp. 2d 704, 721-22 (E.D. Tenn. 2001).

[3] Although the MDL Court did not dismiss Plaintiff's fraud claim on this ground, it recognized that courts have repeatedly found fraudulent concealment claims duplicative of failure-to-warn claims in actions just like this. *See In re Neurontin*, 618 F. Supp. 2d at 113-14.

Tipton v. Michelin Tire Co., 101 F.3d 1145, 1150-51 (6th Cir. 1996).[4]

B. Pfizer Had No Duty To Warn Of Information It Did Not Know And Could Not Have Known At The Time Mr. Smith Was Prescribed And Took Neurontin

While a plaintiff may ordinarily prove that a product is unreasonably dangerous under either a prudent manufacturer or consumer expectations test, the Tennessee Supreme Court has explained that the consumer expectation "test can only be applied to products about which an ordinary consumer would have knowledge." *Ray ex rel. Holman v. BIC Corp.*, 925 S.W.2d 527, 531 (Tenn. 1996).

> By definition, it could be applied only to those products in which "*everyday experience* of the product's users permits a conclusion. . . ." For example, ordinary consumers would have a basis for expectations about the safety of a can opener or coffee pot, but, perhaps, not about the safety of a fuel-injection engine or an air bag.

Id. (ellipsis in original; citation omitted); *see also Brown v. Raymond Corp.*, 432 F.3d 640, 644 (6th Cir. 2005) ("[S]everal decisions have recognized that 'the prudent manufacturer test will often be the *only* appropriate means for establishing the unreasonable dangerousness of a

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[4] To the extent the Court nevertheless determines to provide a separate instruction on fraud by omission or fraudulent concealment, Plaintiff must prove each of the elements of a fraudulent misrepresentation claim. Therefore, the "plaintiff must show that: '1) the defendant made a representation of an existing or past fact; 2) the representation was false when made; 3) the representation was in regard to a material fact; 4) the false representation was made either knowingly or without belief in its truth or recklessly; 5) plaintiff reasonably relied on the misrepresented material fact; and 6) plaintiff suffered damage as a result of the misrepresentation.'" *Walker v. Sunrise Pontiac-GMC Truck, Inc.*, 249 S.W.3d 301, 311 (Tenn. 2008) (citation omitted); *see also Jenkins v. Brown*, No. M2005-02022-COA-R3-CV, 2007 WL 4372166, at *13 & n.25 (Tenn. Ct. App. Dec. 14, 2007); *First Nat'l Bank v. Brooks Farms*, 821 S.W.2d 925, 927 (Tenn. 1991). In addition, over and above the elements of fraudulent misrepresentation, in order to establish a fraudulent concealment, a plaintiff must prove that the defendant concealed or suppressed a material fact while under a duty to disclose that fact, with the intent to defraud. *See Chrisman v. Hill Home Dev., Inc.*, 978 S.W.2d 535, 538-39 (Tenn. 1998); *Tennessee Pattern Jury Instructions-Civil* § 8.38 (9th ed. 2009) (Misrepresentation by Concealment). Further, a plaintiff must have reasonably relied upon the resulting misrepresentation, thereby suffering injury. *See Chrisman*, 978 S.W.2d at 538-39.

Likewise, if breach of the implied warranty of fitness for a particular purpose is submitted to the jury, it would have to be instructed regarding the additional element that Mr. Smith or his physician relied on Pfizer's skill or judgment in purchasing Neurontin. *See* Tenn. Code Ann. § 47-2-315 (West 2002); *see also* UCC § 2-315, cmt. 1, 1B U.L.A. 8 (2004); *Travelers Indem. Co. v. Indus. Paper & Packaging Corp.*, No. 3:02-CV-491, 2006 WL 3864857, at *10 (E.D. Tenn. Dec. 18, 2006).

complex product about which an ordinary consumer has no reasonable expectation.'") (quoting *Ray*, 925 S.W.2d at 531).

In *Jackson v. General Motors Corp.*, 60 S.W.3d 800 (Tenn. 2001), the Tennessee Supreme Court further explained that, while the TPLA "permit[s] application of the consumer expectation test in all products liability cases in which a party intends to establish that a product is unreasonably dangerous," *id.* at 804, it was still incumbent upon a plaintiff to "present evidence that the ordinary consumer *has* an expectation regarding the safety of the product." *Id.* (emphasis added). To meet that burden, a plaintiff must be able to show that "the average consumer would have sufficient knowledge or familiarity to be able to form reasonable expectations of the product's safety." *Irion*, 2004 WL 746823, at *5; *see also Privette*, 79 Fed. Appx. at 888; *King v. Danek Med., Inc.*, 37 S.W.3d 429, 436 (Tenn. Ct. App. 2000). Specifically addressing *Jackson*, the Sixth Circuit has stated:

> The *Jackson* Court, however, limited this holding by repeating its earlier warning that "plaintiffs in cases involving highly complex products" will often be unable "to establish that the product is dangerous to an extent beyond that which would be contemplated by an ordinary consumer, even though the consumer expectation test may, technically, apply."
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> Furthermore, courts applying the TPLA since *Jackson* have continued to rule that the complexity of a product forecloses the use of the consumer-expectation test.

Brown, 432 F.3d at 644 (citations omitted); *see also id.* at 644-45 (holding that trial court correctly applied the prudent manufacturer test rather than the consumer expectation test).

All prescription medicines carry risks, and the ordinary consumer lacks sufficient experience to form reasonable expectations about the adequacy of warnings included on a prescription drug label in light of the relevant scientific information. *See Pittman v. Upjohn Co.*, 890 S.W.2d 425, 431 (Tenn. 1994) ("'Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect.'") (citation omitted); *Taylor v. Merck & Co.*, No. 08-2244, 2009 WL 3429685, at *3 (W.D. Tenn. Oct. 16, 2009) ("Acceptable risk tolerances for prescription medications are not within a layman's common knowledge.") As a result, the

relevant test to be applied here is the prudent manufacturer test.[5]

A manufacturer is not required to make the product "perfect, or render the product accident proof or incapable of causing injury." *Curtis ex rel. Curtis v. Universal Match Corp.*, 778 F. Supp. 1421, 1430 (E.D. Tenn. 1991), *aff'd mem. sub nom. Curtis ex rel. Curtis v. Pope & Talbot, Inc.*, 966 F.2d 1451 (6th Cir. 1992); *see also id.* at 1429-30 (granting summary judgment for failure to offer any evidence of defectiveness). And, as this Court has observed, "it is a matter of common sense and Tennessee law that simply because a product 'cause[s] death' in certain circumstances does not make the product unreasonably dangerous." *Lee v. Metro. Gov't of Nashville & Davidson County*, 596 F. Supp. 2d 1101, 1130 (M.D. Tenn. 2009) (Trauger, J.) (alteration in original).

"Warnings concerning prescription drugs generally are adequate when they contain a full and complete disclosure of the potential adverse reactions to the drug." *Pittman*, 890 S.W.2d at 429. In addition, "[t]he adequacy or need for a warning should be evaluated in light of the expertise of the users of the product. Where a product is marketed solely to professionals experienced in using the product, the manufacturer may rely on the knowledge that a reasonable professional would apply in using the product." *Id.* at 430 (citations omitted). Because Tennessee recognizes the learned intermediary doctrine, *see id.* at 429, "[p]hysicians are, under this analysis, users of prescription drugs." *Id.* at 430.

It is axiomatic that a defendant cannot be liable for failing to warn of alleged risks that it did not know, and could not have known through the exercise of reasonable care. *See, e.g.*, *Kibbler v. Richards Med. Co.*, No. 02A01-9110-CV-00214, 1992 WL 233027, at *2 (Tenn. Ct. App. Sept. 23, 1992); *Browder v. Pettigrew*, 541 S.W.2d 402, 404 (Tenn. 1976); *see also* Tenn. Code Ann. § 29-28-105(b) (West 2002) (the state of scientific and technological knowledge available to the manufacturer at the time the product was placed on the market, rather than at the

[5] Alternatively, if the jury is instructed regarding the consumer expectation test, the learned intermediary doctrine requires that the jury be instructed that the relevant consumer is the physician. *See Pittman*, 890 S.W.2d at 430; *Harden v. Danek Med., Inc.*, 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998).

time of injury, is applicable). In this case, Plaintiff will be unable to produce sufficient evidence to satisfy her burden on this issue.

As the MDL Court observed, "[t]he 'gold standard' for determining the relationship between a drug and a health outcome is a randomized, double-blind, placebo-controlled clinical trial." *In re Neurontin Mktg., Sales Practices, & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 125 (D. Mass. 2009) [MDL Docket No. 1775]. Here, it is undisputed that the controlled clinical data for Neurontin fail to show a statistically significant increased risk of suicidal events. *See id.* at 140. In fact, Plaintiff and her experts have repeatedly admitted that the Neurontin-specific clinical trial data show *no statistically significant increased risk of*, or association with, suicide-related events. Plaintiff's experts, like the FDA, rely on the *pooled* meta-analysis of clinical trial data for eleven different AEDs, which resulted in the 2008 FDA Alert and, ultimately, the 2008 revised class-wide AED warnings on suicidal events. But Pfizer obviously did not possess such data on other AEDs, from which both the FDA and Plaintiff's experts have extrapolated, *see id.* at 143-44, prior to the FDA Alert, much less in 2004, at the time Neurontin was last prescribed to and taken by Mr. Smith. Indeed, Plaintiff's claims pre-date, by many years, the FDA Alert and meta-analysis, on which Plaintiff's experts' opinions, and the revised FDA warning, are based. Plaintiff's experts cannot point to any other epidemiological study in support of their opinions that Neurontin can cause suicide, or any reliable scientific evidence of causation that existed, and should have been known to Pfizer, at the time period relevant to this action. *See id.* at 133-37.

Plaintiff cannot, in the undisputed absence of any evidence of an association in the controlled clinical trial data for Neurontin, or any other controlled epidemiological data pre-dating the FDA's 2008 meta-analysis, rely on mere cherry-picked anecdotal evidence, such as case reports and adverse event reports, to satisfy her burden to show that Pfizer had knowledge triggering a duty to warn about suicide. As the MDL Court recognized in its *Daubert* ruling on general causation, such evidence cannot, on its own, establish an association between a drug and a side effect, much less demonstrate a causal relationship, because there is no control group. *See In re Neurontin*, 612 F. Supp. 2d at 136-37, 153, 157. (*See also* Letter from Russell

Katz, M.D., Food and Drug Administration, to Andrew G. Finkelstein, dated Apr. 12, 2005 (responding to Plaintiff's counsel's letter providing "MedWatch forms of patients whom [Mr. Finkelstein] state[d] committed suicide while being treated with Neurontin" and emphasizing that, "in the absence of an appropriate control group, it will be difficult, if not impossible, to assess the role of any other factors that might explain these events, such as concomitant medications"); e-mail from Donald Dobbs, Food and Drug Administration to Alexander Ruggieri, M.D., dated Apr. 1, 2008 ("[T]he agency does not believe that spontaneous post-marketing reports can be interpreted appropriately in this situation. Patients taking these drugs have a high background rate of suicidal thoughts/behaviors, and it is not possible to tell from AERS reports, whether the drug caused them. In the agency's view, the only way to establish whether or not the drugs are responsible for suicidality is to analyze controlled trial data.").)

In addition, a product is presumed not defective or unreasonably dangerous if the manufacturer has complied with applicable regulations governing the alleged defect. *See* Tenn. Code Ann. § 29-28-104 (West 2002). In this case, Plaintiff contends that Neurontin was unreasonably dangerous because it did not have a warning regarding the risk of suicide or suicidal behavior. However, it is undisputed that, at the relevant time, the label was approved by the FDA without a suicide warning. *See infra* Section III.B.[6]

In sum, Pfizer cannot be held liable for failing to warn Mr. Smith's prescribing doctors of a risk of suicide when the label was approved by the FDA and the evidence on which Plaintiff relies to support her arguments on causation did not become available until many years later.

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[6] Plaintiff may argue that the presumption does not apply here, where the product was prescribed off-label. However, there is no evidence that the decedent's prescribing physician was exposed to any alleged off-label marketing. Regardless, it is irrelevant to the adequacy of the label. The FDA approved Neurontin as adjunctive therapy for epilepsy and for treatment of post-herpetic neuralgia, a form of neuropathic pain. There is no basis to believe that the FDA would have required additional warnings if the approved indications had been broader.

II. Plaintiff Bears The Burden Of Proving Causation

A. Plaintiff Must Prove That Neurontin Was A "But-For" Cause Of Mr. Smith's Suicide

As both this Court and the MDL Court have recognized, Plaintiff cannot prevail unless she can prove medical causation. To do so, she must establish both general causation, that is, that Neurontin is capable of causing suicide, and specific causation, that is, that Neurontin caused Mr. Smith's suicide. *See In re Neurontin*, 612 F. supp. 2d at 123. (*See also* Feb. 19, 2010 Mem. [MDTenn. 63] at 9.)

In order to meet her burden of proof on medical causation, Plaintiff must prove that Neurontin was a "but-for" cause of Mr. Smith's suicide, and not merely that Neurontin was a contributing factor in his death. *See Mason ex rel. Mason v. Metro. Gov't of Nashville & Davidson Cty.*, 189 S.W.3d 217, 221 (Tenn. Ct. App. 2005); *see also Hale v. Ostrow*, 166 S.W.3d 713, 718 (Tenn. 2005) (a plaintiff seeking to establish causation must show that the defendant's conduct was a "but for" cause of the plaintiff's injury); *Waste Mgmt., Inc. of Tenn. v. S. Cent. Bell Tel. Co.*, 15 S.W.3d 425, 430-31 (Tenn. Ct. App. 1997) ("Tennessee's courts have consistently recognized that conduct cannot be a cause in fact of an injury when the injury would have occurred even if the conduct had not taken place. This principle has come to be known as the 'but for' test.") (citations omitted).

A causal connection between Neurontin and Mr. Smith's suicide cannot be left to the jury's conjecture or speculation. *See Moon v. Johnson*, 47 Tenn. App. 208, 217-18, 337 S.W.2d 464, 469 (1959); *accord Morris v. Wal-Mart Stores, Inc.*, 330 F.3d 854, 865 (6th Cir. 2003) (applying Tennessee law). To make such a showing, Plaintiff "'must introduce evidence which affords a reasonable basis for the conclusion that it is more likely than not that the [suicide] was [caused by Neurontin]. A mere possibility of such causation is not enough.'" *Morris*, 330 F.3d at 865 (quoting *Lindsey v. Miami Dev. Corp.*, 689 S.W.2d 856, 861 (Tenn. 1985)).

B. Plaintiff Must Establish General Causation

Plaintiff cannot prevail at trial unless she can make a threshold showing, through expert

evidence, that "Neurontin is capable of causing suicide-related events." *In re Neurontin*, 612 F. Supp. 2d at 123; *see also Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1200-01 (6th Cir. 1988) (applying Tennessee substantive law) (in a case involving complex medical issues, a plaintiff must prove causation based on admissible expert testimony). Pfizer has previously briefed the issue of general causation in detail, and incorporates those arguments herein. (*See* Mem. in Supp. of Defs.' Mot. to Exclude [MDL-1158]; Mem. in Supp. of Defs.' Mot. for Summ. J. [MDL-1162].) As Pfizer has argued and will establish at trial, Plaintiff cannot satisfy her burden to prove general causation, because the experts on which she relies have employed flawed methodologies in reaching their conclusions and because the overwhelming weight of reliable, epidemiologic evidence shows *no association* between Neurontin and suicide-related events.

Plaintiff's experts rely not upon controlled clinical trials to support their opinions, but upon anecdotal adverse event data, which numerous courts have recognized cannot establish causation.[7] Likewise, evidence of the FDA's 2008 Alert and meta-analysis of data on antiepileptic drugs (AEDs), and any post-2004 regulatory action relating to Neurontin's labeling, proves neither causation nor failure to warn. Initially, "the decision by the FDA to require warnings on a drug label, without more, does not suffice to establish causation," *Neurontin Marketing*, 612 F. Supp. 2d at 137, because "the FDA often uses a different standard than a court does to evaluate evidence of causation in a products liability action." *Id.* at 136; *see also Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) (finding FDA regulatory "balancing" and warnings "irrelevant in determining the threshold question of causation"). Moreover, the FDA Alert is not based on specific conclusions about Neurontin specifically, but rather on analysis of pooled or combined placebo-controlled clinical trial data for eleven different AEDs. The "pooled" data set that produced those figures is comprised of the aggregated data for eleven different drugs with different pharmacologic properties, chemical

[7] *See* Memorandum of Law in Support of Defendants' Motion to Exclude Anecdotal Adverse Event Reports [MDTenn 110].

structures, mechanisms of action and safety profiles. Significantly, the FDA pooled data is inconsistent with Neurontin specific data.[8]

Plaintiff also seeks to rely upon two recently disclosed articles: E. Patorno et al, "Anticonvulsant Medications and the Risk of Suicide, Attempted Suicide, or Violent Death," JAMA (April 14, 2010), and J. B. Olsen et al., "Antiepileptic drugs and risk of suicide: a nationwide study," Pharmacoepidemiology and Drug Safety (2010). Due to their recent disclosure, Pfizer has not yet completed the depositions of Plaintiff's experts regarding their reliance on these articles. Nonetheless, the evidence at trial will show that these studies do not establish the a higher incidence of suicide among patients taking Neurontin than in patients unexposed to any drug (the only association that is relevant),[9] and are inconsistent with and contradicted by other studies that do compare Neurontin exposure to no exposure.[10]

C. Plaintiff Must Establish Specific Causation

Plaintiff must prove that, but for Pfizer's conduct, Mr. Smith would not have committed suicide. *See Mason*, 189 S.W.3d at 221. Defendants have previously briefed the issue of specific causation and incorporate by reference their prior Motion for Summary Judgment (*Smith*) [MDL-1641]; Motion to Exclude the Specific Causation Testimony of Doctor Ronald William Maris and Professor Michael Trimble (*Smith*) [MDL-1627]; and Motion for Summary Judgment [MDTenn 17], together with all memoranda of law filed in support of such motions.

D. Plaintiff Must Establish Proximate Cause

Plaintiff must also establish proximate causation. *See Johnson v. Settle*, No. M1999-01237-COA-R3-CV, 2001 WL 585093, at *6 (Tenn. Ct. App. June 1, 2001). Defendants have previously briefed this issue and incorporate by reference their Motion for Summary Judgment

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[8] The MDL Court has acknowledged that Pfizer's expert, Dr. Robert Gibbons, "has presented a powerful critique of the [FDA meta-analysis]," Plaintiff's primary evidence on causation. *In re Neurontin*, 612 F. Supp. 2d at 139.

[9] *See* Reference Manual on Scientific Evidence at 338 (2d ed. 2000).

[10] In addition, because the articles were published in 2010, they are not relevant to Pfizer's duty to warn in 2004. *See supra* Section I.B.

[MDTenn 17], together with supporting memoranda of law.

III. Plaintiff Will Be Unable To Establish The Elements Of Her Claim For Punitive Damages

A. The Standard Governing Punitive Damages

Under Tennessee law, "punitive damages are to be awarded only in the most egregious of cases." *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896, 901 (Tenn. 1992). "Further, because punitive damages are to be awarded only in the most egregious of cases,[11] a plaintiff must prove the defendant's intentional, fraudulent, malicious, or reckless conduct by clear and convincing evidence." *Id.*; *see also id.* at 900-01 (under Tennessee law, punitive damages may not be awarded for "gross negligence"). Plaintiff cannot meet this standard because she has no evidence of intentional, fraudulent, malicious, or reckless conduct. Pfizer's warnings have always complied with FDA requirements and Plaintiff has no credible evidence of a duty to warn of suicide, much less a malicious or intentional failure to do so, at the time period relevant to this action or at any other time.

B. Plaintiff Should Not Be Permitted To Convert A Failure To Warn Case Into A Punitive Damages Case

All of the evidence upon which Plaintiff relies to establish an alleged duty to warn was fully disclosed to the FDA in conformance with Pfizer's regulatory obligations. And it is undisputed that the FDA evaluated all of this same data and repeatedly approved the Neurontin label without a suicide warning. For example, Plaintiff places great reliance on a statement appearing in the 1992 FDA Combined Medical-Statistical Review of Neurontin, which she seeks to isolate from a thorough and complex review process that lasted several years. While the evidence at trial will show that Plaintiff has taken this statement out-of-context and

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[11] In *Goff v. Elmo Greer & Sons Constr. Co.*, 297 S.W.3d 175 (Tenn. 2009), *cert. denied*, No. 09-921, 2010 WL 390377 (U.S. Mar. 22, 2010), the Tennessee Supreme Court stated: "[T]rial courts would do well to explicitly charge that punitive damages are reserved for egregious conduct as a way of crystalizing the point that punitive damages do indeed represent 'strong medicine.'" *Id.* at 197. Consistent with *Goff*, Defendants have included such language in their proposed jury instruction on punitive damages.

misinterpreted it, it is undisputed that, in December 1993, the FDA approved Neurontin for use as adjunctive therapy in the treatment of epilepsy and approved Neurontin's label without a suicide warning. Again, in May 2002, when it approved Neurontin for use in the treatment of post-herpetic neuralgia, the FDA, having reviewed all the available data (including clinical trials and post-marketing adverse event reports), did not require a suicide warning. In 2005, the FDA again approved the Neurontin label without a suicide warning, even after specifically reviewing case reports of suicide and suicide attempts collected from clinical trial and post-market surveillance data.

Indeed, Judge Saris reviewed the exact same evidence relied upon by Plaintiff to support her generic causation claims and, while concluding that the MDL plaintiffs[12] had marshaled enough evidence to survive a *Daubert* challenge,[13] she nonetheless acknowledged that there is a robust scientific debate regarding the association between Neurontin and suicide. Initially, the 2008 FDA meta-analysis was central to Judge Saris's conclusion that the MDL plaintiffs had made a sufficient showing of an association between Neurontin and suicide. *See In re Neurontin*, 612 F. Supp. 2d at 158 ("Most significantly, the FDA study provides evidence of an association between Neurontin and an increased risk of suicidality, the prerequisite for a causation analysis Bradford Hill criteria."). It is undisputed that the FDA's study was based upon a meta-analysis data collected from different manufacturers regarding eleven different anti-epileptic drugs ("AEDs"). Such data could not have been available to Pfizer in 2004. It is also undisputed that the Neurontin-specific data reviewed by the FDA as part of the meta-analysis did not demonstrate a statistically significant association with suicidality events. *See id.* at 140 ("Still, the FDA study is not a silver bullet for Plaintiffs. Standing alone, the Neurontin-specific data produced a positive association, but not a statistically significant one.").

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[12] The MDL plaintiffs included Ms. Smith.

[13] Defendants respectfully disagree that the evidence of generic causation is sufficient to satisfy the dictates of *Daubert*. However, regardless of whether the evidence is sufficient to support liability for failure to warn and compensatory damages, it is clear, for the reasons stated above, that it cannot support an award of punitive damages.

Judge Saris also acknowledged the limitations on the FDA study and the legitimate debate regarding its conclusions. For example, she noted that "[i]t is widely recognized that, when evaluating pharmaceutical drugs, the FDA often uses a different standard than a court does to evaluate evidence of causation in a products liability action." *Id.* at 136. She also observed that defense expert "Dr. Gibbons has presented a powerful critique of the FDA's statistical analysis and its conclusion that the increased risk of suicidality detected in its meta-analysis is 'consistent among the group of 11 drugs.'" *See id.* at 139. At the same time, Judge Saris acknowledged that a statistical association between Neurontin and suicidality had not been found in any Neurontin clinical trials. *See id.* at 140-41.[14]

Likewise, with respect to the MDL plaintiffs' theory regarding mechanism of action, Judge Saris once again concluded that "there is a robust debate in the scientific community on whether gabapentin decreases the release of monoamines." *Id.* at 149. For example, Judge Saris noted that a 1992 double-blind placebo-controlled experiment demonstrated no affect of gabapentin on dopamine and serotonin levels. *See id.* at 148. She also stated: "What is hotly disputed is whether gabapentin causes any such decrease in monoamines. In this battle, both sides present peer-reviewed studies to support their position." *Id.* at 158. Regarding adverse event reports, the other piece of evidence relied upon by Plaintiff to support her failure to warn claims, Judge Saris observed: "To be sure, Plaintiffs and Defendants agree that adverse event reports ('AERs') – whether published in safety databases or the medical literature – have significant limitations." *Id.* at 153.[15] Judge Saris recognized additional criticisms of the MDL

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[14] In response to Defendants' *Daubert* motions, the MDL plaintiffs cited only one epidemiologic study other than the FDA meta-analysis to support their claims of causation – the Collins & McFarland study. Judge Saris agreed that "Defendants have the better argument that it does not provide independent proof of an association or causation." *See In re Neurontin*, 612 F. Supp. 2d at 145.

[15] Courts have repeatedly recognized that adverse event reports are insufficient evidence of causation. *See, e.g., McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (noting that adverse event reports are "[u]ncontrolled anecdotal information offer[ing] one of the least reliable sources to justify opinions about both general and individual causation"); *In re Accutane Prods. Liab.*, No. MDL 1626, 2007 WL 1288354, at *3 (M.D. Fla. May 2, 2007) (noting that adverse event reports "reflect[] nothing more than an assessment of a possible relationship, not an actual relationship").

plaintiffs' expert analysis. For example, while plaintiffs' expert Dr. Cheryl Blume purported to identify 25 positive dechalllenge events that she concluded were potentially related to gabapentin, Judge Saris observed: "Notably, none of these twenty-four events involved specifically suicidal behavior, but rather entailed depression (one case) and "psychobiological events" such as hostility, emotional liability, thinking abnormally, nervousness, and confusion." *Id.* at 155.

In short, the record in this case establishes that in its labeling of Neurontin's potential risks, Pfizer complied with the extensive federal regulatory scheme governing prescription drug labeling, and that there is continuing disagreement and debate in the scientific community over the question of whether Neurontin can cause suicidal behavior. In order to find for Plaintiff on her failure to warn claim and award *compensatory* damages, the jury will have to second-guess the FDA's decision *not* to require a suicide warning on the Neurontin label prior to 2009 and to agree with the Plaintiff's experts' interpretation of the available data. While Defendants contend that the evidence at trial will be insufficient to meet Plaintiff's burden as to liability for compensatory damages, it is apparent on the existing record that it cannot support an award of punitive damages.

To be clear, this is not an argument of federal preemption. Rather, Defendants contend, first, that the evidence relied upon by Plaintiff is insufficient, as a matter of law, to establish, by clear and convincing evidence, the degree of culpability required for punitive damages. This is especially true in light of Tennessee's statutory presumption that a product that complies with government regulations is not defective or unreasonably dangerous. As the Tennessee Supreme Court has explained, this presumption "was designed 'to give refuge to the manufacturer who is operating in good faith and [in] compliance of what the law requires him to do.'" *Flax v. DaimlerChrysler Corp.*, 272 S.W.3d 521, 536 (Tenn. 2008), *cert. denied*, 129 S. Ct. 2433 (2009).

Second, imposing punitive damages on the facts of this case would result in a denial of Pfizer's due process rights. Where a defendant has ordered its behavior in a way it justifiably believed to be reasonable and lawful, the infliction of punishment for that conduct "depart[s] from the fundamental principles of justice embraced in the recognized conception of due process

of law" and is "so plainly arbitrary and oppressive as to be nothing short of a taking of [the defendant's] property without due process of law." *Sw. Tel. & Tel. Co. v. Danaher*, 238 U.S. 482, 490-91 (1915). It is, therefore, a matter of due process that the law provide manufacturers with fair notice of the nature of wrongdoing that may subject them to punitive liability. *See BMW of North America, Inc. v. Gore*, 517 U.S. 559, 574 (1996).

Indeed, federal and state courts have repeatedly barred claims for punitive damages where there is a disagreement among experts over the safety of a product, a genuine dispute in the scientific community, or where the defendant has complied with the relevant regulatory scheme. *See, e.g., Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1317 (5th Cir. 1995) (vacating punitive damages award in motorcycle design defect action, citing, inter alia, a "genuine dispute in the scientific community as to whether leg guards do more harm than good");[16] *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994) (vacating punitive damages in tire defect case, holding judgment as a matter of law was proper as to punitive damages claim because the defendant "complied with all requisite Federal Motor Vehicle Safety Standards");[17]

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[16] *See also Burke v. Deere & Co.*, 6 F.3d 497, 511 (8th Cir. 1993) (reversing punitive damages award in action alleging failure to adequately warn of safety risks of John Deere combine, observing: "An award of punitive damages is not appropriate when room exists for reasonable disagreement over the relative risks and utilities of the conduct at issue."); *AMPAT/Midwest, Inc. v. Ill. Tool Works Inc.*, 896 F.2d 1035, 1044 (7th Cir. 1990) (affirming order setting aside punitive damages given the "disagreement between [experts] over the gravity of the defects" in defendant's masonry products and about causation of damages); *Kehm v. Procter & Gamble Mfg. Co.*, 724 F.2d 613, 623 (8th Cir. 1983) (finding trial court erred in submitting punitive damages question to jury in tampon toxic shock syndrome ("TSS") case where there was "voluminous evidence produced at trial regarding the speculation and uncertainty . . . as to the cause of TSS"); *Berroyer v. Hertz*, 672 F.2d 334, 342 (3d Cir. 1982) (reversing punitive damages award in dental malpractice action where "a difference of medical opinion [among experts] on the degree of the cancer risk" to plaintiff provided "insufficient support" for punitive damages); *Hillrichs v. Avco Corp.*, 514 N.W.2d 94, 100 (Iowa 1994) (affirming reversal of punitive damages award where evidence showed there was "room for reasonable disagreement over" the reasonableness of manufacturer's decision to not install emergency stop device in cornpicker).

[17] *See also Drabik v. Stanley-Bostich, Inc.*, 997 F.2d 496, 510 (8th Cir. 1993) (vacating same in action alleging injury from defective pneumatic nailer, noting, "[c]ompliance with industry standard and custom serves to negate conscious disregard and to show that the defendant acted with a nonculpable state of mind"); *Boyette v. L.W. Looney & Son, Inc.*, 932 F. Supp. 1344, 1348 (D. Utah 1996) (dismissing punitive damages claim in action alleging failure to warn of explosive nature of foam product where, *inter alia*, manufacturer complied with OSHA regulations); *Welch v. Gen. Motors Corp.*, 949 F. Supp. 843, 845 (N.D. Ga. 1996) (granting summary judgment on punitive damages claim in defective brakes case *(cont'd)*

cf. W. Page Keeton, *Prosser & Keeton on the Law of Torts* 233, n.41 (5th ed. 1984) ("In most contexts . . . compliance with a statutory standard should bar liability for punitive damages.").

In the case of prescription medicines, for example, pharmaceutical manufacturers must be permitted to proceed on the principle that if they disclose the risks of their medicines in a manner consistent with the extant scientific evidence – even if that evidence is equivocal or uncertain – and comply with the FDA's rigorous review and approval of the product's testing and labeling, that conduct will not, in hindsight, be deemed so wanton or reckless as to permit punitive damages. That is precisely the case here, where, even if there were legally sufficient evidence to support a finding that Defendants should have known and warned of a risk of suicidal behavior in 2004 (and there is not), the 2004 Neurontin label was the product of appropriate and considered scientific judgments under the close scrutiny of the FDA. In view of Pfizer's compliance with the FDA regulatory regime and the continuing scientific debate over the underlying issue of causation, Plaintiff cannot show that Pfizer's failure to include a warning about suicidal behavior in the 2004 Neurontin label constituted conduct that would entitle her to seek punitive damages.

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where "the defendant complied with the applicable federal regulations"); *Sloman v. Tambrands, Inc.*, 841 F. Supp. 699, 703 n.8 (D. Md. 1993) (finding plaintiff in tampon TSS case not entitled to punitive damages where defendant complied with FDA safety warning requirements); *Stone Man v. Green*, 435 S.E.2d 205, 206 (Ga. 1993) (reversing punitive damages award because defendant quarry operator complied with applicable mining standards and "compliance with county, state, and federal regulations is not the type of behavior which supports an award of punitive damages"); *Chrysler Corp. v. Wolmer*, 499 So. 2d 823, 826 (Fla. 1986) (reversing district court's decision to reinstate punitive damages where it was undisputed that "Chrysler tested its product and . . . the fuel system in the [vehicle] satisfied" the regulatory standard).

C. The Jury Must Be Instructed Consistent With the Supreme Court's Dictates in *Campbell* and *Philip Morris*[18]

For the reasons discussed above, Pfizer submits that the evidence in this case will not support submission of punitive damages to the jury. If, however, the jury is instructed on punitive damages, those instructions must comport with U.S. Supreme Court precedent.[19]

In *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), the United States Supreme Court held that, as a matter of due process, "[a] defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages." *Campbell*, 538 U.S. at 422-23. The Court explained that "[a] defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business." *Id.* at 423. Moreover, the Court stated that "[d]ue process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis." *Id.*

In *Campbell*, the Supreme Court held unconstitutional the lower court's punishment of twenty years of various dissimilar conduct by the defendant, explaining that courts are not permitted "to expand the scope of the case so that a defendant may be punished for any malfeasance." *Id.* at 424. Punishment based on dissimilar conduct "creates the possibility of

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[18] The U.S. Supreme Court's decisions in *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003) and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007) post-date, by several years, the Tennessee Supreme Court's decision in *Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896, 901 (Tenn. 1992), upon which the Tennessee Pattern Jury Instructions are based. For the reasons discussed in this section, Defendants have proposed modifications to the Tennessee Pattern Jury Instructions to the extent they would instruct the jury to consider factors that, on the facts of this case, are irrelevant or which could lead to a disproportionate award in violation of *Campbell* and *Philip Morris*. Defendants have proposed additional language that they believe is required by *Campbell* and *Philip Morris*.

[19] Defendants also incorporate their prior Memorandum Of Law In Support Of Defendants' Motion In Limine To Exclude Evidence Of Marketing Or Advertising Materials And Conduct And Other Litigations [MDTenn 116] and Defendants' Motion *In Limine* To Exclude All Evidence Of Or References To Warner-Lambert Company LLC's Guilty Plea Or Any Related Government Investigations Or Agreements [MDTenn 125]. For the reasons discussed therein, Defendants respectfully maintain that punitive damages may not be awarded based upon dissimilar conduct, including conduct admitted to in Warner Lambert's 2004 criminal plea.

multiple punitive damages awards for the same conduct" since "nonparties are not bound by the judgment some other plaintiff obtains." *Id.* at 423. A punitive damages award based on conduct unrelated to the plaintiff's harm enters the "zone of arbitrariness" that violates due process. *See BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 568 (1996).

Later, the Supreme Court explicitly clarified that due process "forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties . . . , i.e., injury that it inflicts upon those who are, essentially, strangers to the litigation." *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007); *see also Campbell*, 538 U.S. at 423 ("Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis . . . ."). To allow punitive damages to be based upon harm to non-parties would violate due process by denying the defendant "'an opportunity to present every available defense.'" *Philip Morris*, 549 U.S. at 353 (quoting *Lindsey v. Normet*, 405 U.S. 56, 66 (1972)).

The Supreme Court further explained that "to permit punishment for injuring a nonparty victim would add a near standardless dimension to the punitive damages equation," magnifying the due process risks of "arbitrariness, uncertainty and lack of notice," *Id.* at 354. Finally, the Court stated, there is "no authority supporting the use of punitive damages awards for the purpose of punishing a defendant for harming others." *Id.* The Court "made clear that the potential harm at issue was harm potentially caused *the plaintiff*." *Id.* (emphasis in original). Thus, in *Philip Morris*, the Supreme Court held that the jury must be correctly instructed according to the standards stated by the Supreme Court to assure that the jury is not imposing punishment for conduct unrelated to the injury to Plaintiff. *See id.*

CONCLUSION

Defendants respectfully request that the Court consider this memorandum in further support of their proposed jury instructions and other trial submissions and arguments.

Dated: May 11, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 11th day of May 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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